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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/713,398

11/14/2003

Makoto Inaba

P/3541-48

9897

2352 7590 08/21/2007
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EXAMINER

HALL, DEANNA K

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

08/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/713,398		INABA, MAKOTO	
	Examiner		Art Unit	
	Deanna K. Hall		3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>November 14, 2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.
2. The information disclosure statement filed November 14, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to **patentability** as defined in **37 CFR 1.56**.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Kalloo et al. (US 2001/0049497) (“Kalloo”).

Kalloo discloses: a first bendable catheter 40 with a bending control section which guides the tube [0028], [0032]; and a second catheter 10 attached to the first catheter holding the insert section, the second catheter comprising at least one retaining portion 22, 24 which is open and closed, to be anchored in the body cavity, by a control section [0031]. The second catheter can maintain the elbow portion in an extended state, see Fig. 12.

It is the examiner's position that some type of anchor section removably anchors the first and second catheters to each other since the overtube 10 of Kalloo provides a sterile pathway then each time the endoscope is used the overtube must be removed and either re-sterilized or replaced with a new overtube.

Kalloo further discloses a hold section, see Fig. 1 attached to the first catheter 40 to support the catheter unit.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 4-5 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalloo in view of King (US 5,702,365).**

Kalloo discloses the invention as substantially claimed (see above).

However, Kalloo fails to disclose the second catheter having an outer sheath and an inner sheath coupled to each other on the distal end with the retaining portion, made of a plurality of slits cut in the outer sheath of the first catheter, opening and closing as the outer sheath is slid relative to the inner sheath. King, in the analogous art, teaches these limitations, see col. 1 lines 30-31 and 41-45, and col. 2 lines 31-38. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the retention balloon of Kalloo with the inner and outer sheaths axial movement opening and closing the slits of the outer sheath of King for retaining the instrument in a desired location.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kalloo in view of King further in view of Urick et al. (US 6,676,590) ("Urick").

The combination of Kalloo and King above teaches opening a retaining portion of the catheter. In addition, Kalloo discloses inserting an endoscope 40 into the body cavity and further discloses how a variety of diagnostic, therapeutic and/or surgical accessories may be fed through the accessory channel(s) 64 of the endoscope, [0048]. Kalloo and King fail to disclose the step of setting a tube (with a radiation source) in the conduit of the catheter to be inserted into the living body cavity. Urick, in the analogous art, teaches the step of setting a tube in the conduit of the catheter, see Fig. 1. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Kalloo/King with the tube set in the conduit as taught by Urick for administering radiation therapy to a living body. The radiation tube could be inserted through the accessory channel 64 of Kalloo.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deanna K. Hall whose telephone number is 571-272-2819. The examiner can normally be reached on M-F 8:00am-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on 571-272-4966. The fax


Art Unit: 3767

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

dkh

Deanna K. Hall
Examiner
AU 3767


LOAN H. THANH
PRIMARY EXAMINER